

EXHIBIT 19



Left Behind:

An Analysis of Charity Care Provided by Hospitals Enrolled in the 340B Drug Pricing Program

February 2022



Executive Summary

The hospitals that participate in the 340B program obtain steep discounts for qualifying prescription medicines, with no obligation that they pass those discounts to patients or reinvest profits from 340B discounts into free or reduced cost care for low-income patients.¹ To examine whether participating hospitals are using 340B revenue to fund free and reduced cost care for uninsured or vulnerable populations, the Alliance for Integrity and Reform of 340B (AIR340B) engaged Avalere Health to analyze charity care provided by 340B hospitals.

One-quarter (25 percent) of 340B DSH hospitals provide charity care that represents less than 1 percent of their total operating costs.

Source: Avalere Health analysis of FY 2019 Medicare cost report data

The findings of this report raise questions regarding whether the eligibility criteria for Disproportionate Share Hospitals

(DSH) are aligned with Congress' goal of supporting access to medicines for uninsured or vulnerable populations.

During the eight years since AIR340B first released an analysis of hospital charity care², the 340B program has more than quadrupled in size (from \$9 billion in 2014 to \$38 billion in 2020)³, and yet most 340B hospitals continue to provide low levels of charity care, as a percent of their operating costs.

The analysis of hospital charity care levels in this report comes from data that hospitals reported in their fiscal year (FY) 2019 Medicare cost reports. The data reveal that many of the hospitals enrolled in the 340B program are providing minimal levels of charity care to vulnerable patients. While some 340B hospitals provide considerable charity care, for one-quarter (25 percent) of 340B DSH hospitals, charity care represents less than 1 percent of total operating costs. The new data also show that about two-thirds (65 percent) of 340B DSH hospitals provide less charity care as a percent of operating costs than the average for all hospitals (340B and non-340B). Consistent with

past analyses,⁴ the data from the FY 2019 cost reports also show that a small share of 340B DSH hospitals (29 percent) account for the bulk of total charity care from all 340B hospitals.

The 340B program has grown dramatically since its inception in 1992, and it is clear the program lacks an adequate structure for accountability and transparency for participating hospitals. Despite continuing widespread support for the program's original safety-net mission, 340B has in reality grown into a profit-driven program. Program growth has been fueled by flawed program guidance, a lack of sufficient oversight, major shifts in the overall health system, and evidence that the program may be leading to market distortions. All of these factors also raise questions about the 340B program's design and sustainability.⁵ These recurring questions and the results of this analysis of charity care highlight the need for change. It is critical that Congress consider revising eligibility criteria for 340B hospitals so that hospital eligibility metrics better target true safety-net hospitals, and not hospitals that provide only a minimal level of charity care.

Background

Congress created the 340B program in 1992 to reinstate the deep discounts that manufacturers had voluntarily provided to many safety-net facilities before the 1990 enactment of the Medicaid drug rebate statute.⁶ This 1990 statute established a nationwide drug rebate program for state Medicaid agencies and set forth a rebate formula that considered the "best price" a manufacturer gave to effectively any customer. Congress failed to exempt manufacturers' voluntary discounts to safety-net providers from Medicaid's "best price," which inadvertently impacted the discounts manufacturers provided. Later in 1992, Congress responded by amending the Medicaid rebate statute to exempt these discounts from "best price" and create the 340B Drug Discount Program, which established discounted prices for eligible safety-net providers based on a specific formula.⁷ These providers, also known as "covered entities," include select federal grantees and certain hospitals.⁸

HOSPITAL ELIGIBILITY FOR THE 340B PROGRAM

Hospital eligibility for the 340B program is defined in the 340B statute. Qualifying nonprofit hospitals can participate in the 340B program and then get discounted medicines for their patients.

In 2004, slightly less than half (49 percent) of 340B sales were to hospitals.⁹ That has shifted over time and more recently about 80 percent of 340B sales were to DSH hospitals,¹⁰ which are the focus of this analysis.¹¹

These hospitals qualify for the 340B program based, in part, on their DSH hospital percentage, which is a measure relating to the share of Medicaid and low-income Medicare patients treated in a hospital's inpatient units and was not developed for application to the 340B program. The DSH hospital metric is used by the Centers for Medicare & Medicaid Services to identify hospitals that qualify for additional Medicare payments based on serving a "significantly disproportionate number of low-income patients."¹² As demonstrated in this paper, a high disproportionate share adjustment percentage is not always linked to high levels of charity care. In fact, declines in charity care due to uninsured patients becoming eligible

for Medicaid through the eligibility expansions under the Patient Protection and Affordable Care Act (ACA) have made more hospitals eligible for 340B as their DSH hospital percentages increase.¹³

The current eligibility criteria have allowed many hospitals to qualify for 340B discounts even though they may not serve significant numbers of vulnerable or uninsured patients and may not provide significant amounts of charity care.

To be eligible for 340B, hospitals must be: (1) owned or operated by a unit of state or local government; (2) a public or private nonprofit hospital formally granted governmental powers by a state or local government; or (3) a private nonprofit hospital contracted with a state or local government to provide health care services to low-income individuals who are not Medicare or Medicaid eligible. Under the program, hospitals that qualify for 340B through a contract obtain 340B discounted medicines for any patient receiving a hospital outpatient service, not merely those patients who receive services related to a hospital's governmental powers or the contracts that make it eligible for 340B participation. Approximately two-

thirds of hospitals that participate in the 340B program are private, nonprofit hospitals that qualify for the program, in part, based on having contracts in place with state or local governments to provide health care services to low-income individuals who are not eligible for Medicare or Medicaid.¹⁴

Recent evidence suggests that the Health Resources and Services Administration (HRSA), which administers the 340B program, may not be providing sufficient oversight of these government contracts to ensure that the eligibility standards are aligned with congressional intent.¹⁵ The legislative history demonstrates that Congress intended that private nonprofit hospitals that contract with a state or local government to provide health care to many “low-income individuals who are not eligible for Medicaid or Medicare” (and met additional requirements) could participate in the 340B program. However, such hospitals could not participate if they only have “a minor contract to provide indigent care which represents an insignificant portion of its operating revenues.”¹⁶

In a report released in December 2019, the Government Accountability Office (GAO) found significant shortcomings in many hospitals’ contracts. Among

other things, few contracts included details about the amount or type of care hospitals were required to provide, and in some instances, documents provided by hospitals were not contracts at all.¹⁷ While HRSA has started reviewing these contracts as part of the annual 340B recertification process, GAO has found that HRSA has not issued guidance that describes how 340B program auditors are to identify whether those contracts meet the standards set by Congress.¹⁸

PAST ANALYSES OF 340B HOSPITALS, THE DSH HOSPITAL METRIC, AND CHARITY CARE

Since 1992, the DSH hospital metric itself has been the subject of careful analyses that have shed light on what it does and does not measure. The analyses call into question the DSH hospital metric’s use in helping determine 340B hospital eligibility.¹⁹ As noted previously, the DSH hospital metric was not designed for 340B eligibility purposes and does not measure the percentage of uninsured patients a hospital serves, or the level of charity care it provides. In 2018, a GAO analysis of hospital charity care found that a fifth of the 340B hospitals in the study were among hospitals that provided the lowest amounts of charity care.²⁰

Additionally, a recent academic study found that hospital enrollment in the 340B program was not associated with an increase in the provision of uncompensated care.²¹ A GAO study also found that the majority of 340B DSH hospitals surveyed do not pass 340B discounts on to low-income, uninsured patients when these patients fill their prescriptions at an outside pharmacy that has a contract with a 340B hospital (known as a contract pharmacy).²²

The 340B program has transformed from a well-intentioned program that was supposed to preserve discounts manufacturers previously offered true safety-net providers before 1992, to one that includes a significantly larger number of hospitals today. Meanwhile, the environment in which nonprofit hospitals operate has also evolved substantially. As highlighted in a 2017 National Academy of Sciences report, “in the years since [340B’s] inception, the structure of hospitals in the United States has dramatically changed, with nonprofit hospitals increasingly displaying characteristics of for-profit hospitals.”²³ That trend, combined with the fact that the DSH hospital metric does not measure the amount of charity care hospitals deliver, raises questions about whether the program is being appropriately targeted to only those

facilities that spend significant resources providing care to disadvantaged populations.

Hospital Charity Care

The charity care data analyzed in this paper reflects the cost of providing free or discounted care to low-income individuals who qualify for a hospital’s charity care program. The analysis focuses solely on charity care and not the broader category of uncompensated care, which includes bad debt from non-indigent and insured patient accounts.

This paper’s primary focus on charity care is consistent with the 340B program’s intent, which is to sustain care for the vulnerable or uninsured.

Many acute care hospitals provide charity care to patients who meet certain income and asset requirements. The specific nature of charity care can vary by hospital, as individual hospitals develop their own policies regarding the criteria individuals must meet to qualify. Although the American Hospital Association’s (AHA) voluntary policies and guidelines for hospitals suggest that care should be provided free of charge to patients below 200 percent of the federal poverty level

who have “a level of [financial] assets appropriate for the community,” there is no requirement that hospitals follow these policies and guidelines.²⁴

IRS regulations require tax-exempt hospitals to establish publicly available written financial assistance policies that apply to all emergency and medically necessary care that hospitals provide.²⁵ Those policies must include eligibility criteria for financial assistance, and whether such assistance includes free or discounted care. The policies must also set forth the basis for calculating amounts charged to patients, and must limit the amount the hospital charges for emergency or medically necessary care it provides to an individual who is eligible for financial assistance, but only to no more than the amount generally billed to individuals who have insurance covering such care.²⁶ However, neither the IRS regulations nor the 340B program requires hospitals to provide free or reduced-price care to low-income uninsured individuals.

Under the IRS regulations, hospitals can set their own eligibility standards for charity care programs. Given this flexibility, the IRS regulations do not appear sufficient to ensure that the nonprofit, tax-exempt hospitals that qualify for 340B fulfill congressional expectations for the 340B program.

This paper analyzes whether current 340B hospital eligibility criteria appropriately target hospitals that provide relatively high levels of free or reduced-price care to vulnerable or uninsured patients.



Methodology

The analysis presented in this paper is based on data obtained from FY 2019 Medicare cost reports analyzed by Avalere Health LLC (Avalere) to determine the share of total hospital costs attributable to charity care, as reported by the hospital (see Appendix A for more information on charity care and data methods).

The paper is based on data from the Medicare cost reports, which are filed annually by hospitals and were redesigned in 2010 to more accurately capture the cost of the charity care that hospitals provide. This Medicare cost report data on charity care was also used by the GAO for a June 2015 report on 340B, in which the GAO stated that it “confirmed with CMS that the agency did not have any concerns about our use of the data.” The GAO also stated that it performed “data reliability assessment and concluded that the cost report data were sufficiently reliable.”

The analysis in this paper excludes Critical Access Hospitals because those rural hospitals have very different cost structures than other hospitals and qualify for 340B based on different metrics (see Appendix B for more information on Critical Access Hospitals).

Additionally, Freestanding Cancer Hospitals, Rural Referral Centers, Children’s Hospitals, and Sole Community Hospitals were excluded from this analysis.

Results of Charity Care Analysis

The findings of this analysis demonstrate that the 340B program includes many hospitals that provide minimal charity care. In fact, for one-quarter (25 percent) of the 340B hospitals studied, charity care represents less than one percent of hospital operating costs (Figure 1). These hospitals provide a level of charity care that is far below the 2.9 percent national average for all short-term acute care hospitals, regardless of 340B status. An additional 40 percent of the 340B hospitals studied provide charity care that represents between 1 percent and 2.9 percent of operating costs. In total, about two-thirds (65 percent) of 340B hospitals provide less charity care than the national average for all hospitals, including for-profit hospitals.

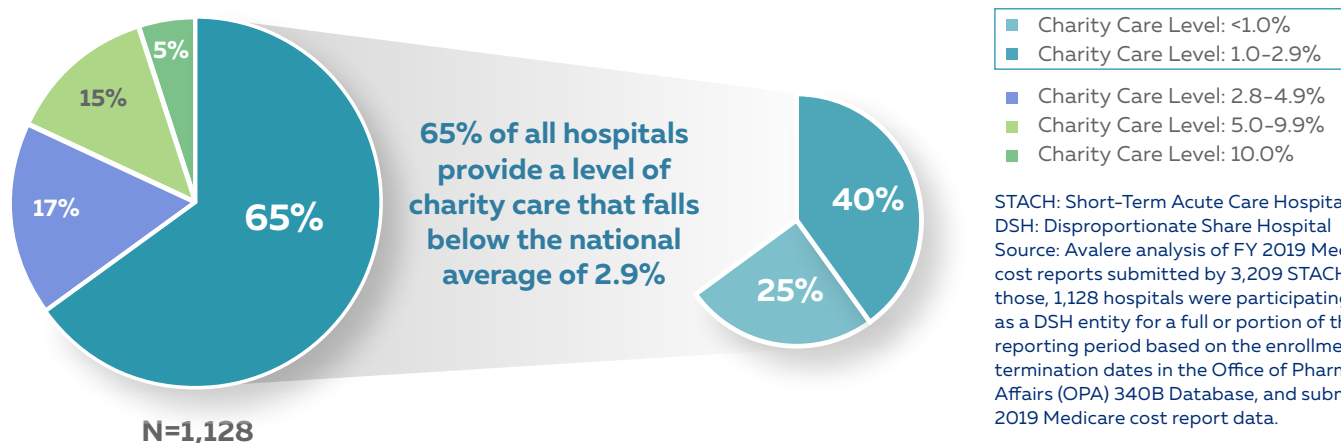
In total, 65 percent of 340B hospitals provide less charity care than the national average for all short-term acute care hospitals, including for-profit hospitals.

Source: Avalere Health analysis of FY 2019 Medicare cost report data

FIGURE 1

About Two-Thirds of 340B DSH Hospitals Provide Below Average Levels of Charity Care

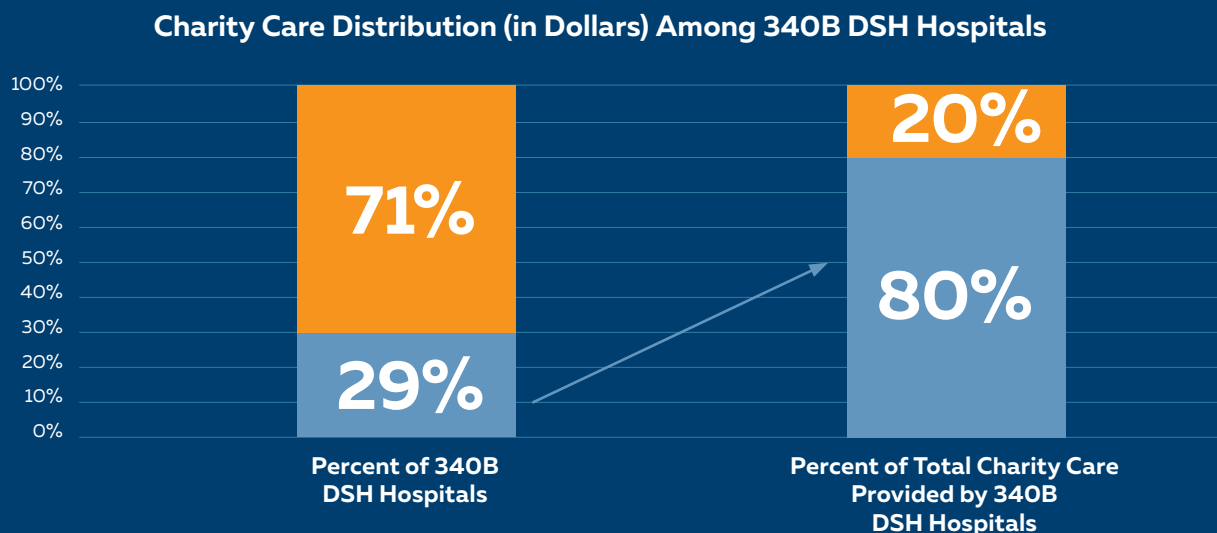
**Charity Care Provided by 340B DSH Hospitals, FY 2019
(As a Percent of Total Operating Costs)**



An analysis of the Medicare cost report data also found that a minority of 340B DSH hospitals provide most of the charity care provided by all 340B hospitals. Specifically, 29 percent of 340B DSH hospitals provide 80 percent of the total charity care provided by all 340B DSH hospitals (Figure 2). Those same hospitals represent only 45 percent of total hospital beds in all 340B facilities. This finding is consistent with an IRS study that found just 9 percent of surveyed nonprofit hospitals were responsible for 60 percent of the community benefit expenditures provided by all of the nonprofit hospitals in the survey.²⁷

FIGURE 2

29% of Hospitals Account for 80% of Charity Care Provided by All 340B DSH Hospitals in FY 2019



Source: Avalere analysis of FY2019 Medicare cost reports submitted by 1,128 hospitals that were participating in 340B as a DSH entity for a full or a portion of their cost reporting period based on the enrollment and termination dates in the Office of Pharmacy Affairs (OPA) 340B Database.

Additional Sources of Government Funding for Hospitals

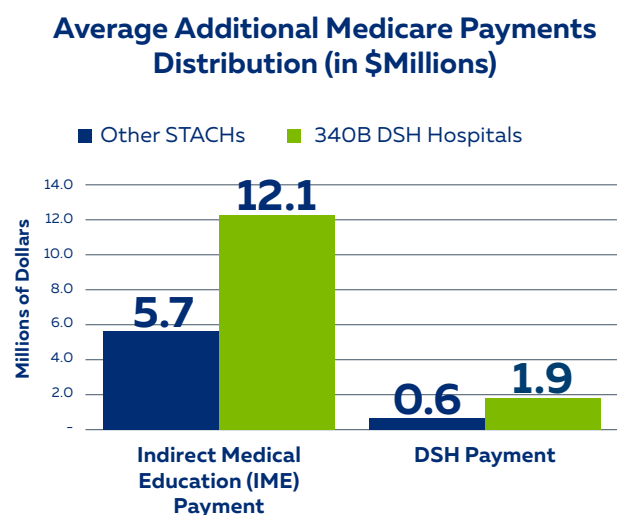
Despite evidence that many hospitals (both 340B and non-340B) provide low rates of charity care, hospitals currently receive government funding from numerous sources to compensate them for the cost of providing charity care and to help absorb the cost of bad debt. Additionally, all hospitals (other than hospitals that are operated by state or local governments) that qualify for 340B are nonprofit, meaning they benefit from being exempt from federal, state, and local taxes. The tax benefits for nonprofit hospitals were most recently valued at \$24.6 billion in 2011.²⁸ A recent report found that “72 percent of private nonprofit hospitals had a fair share deficit, meaning they spent less on charity care and community investment than they received in tax breaks.”²⁹

Some sources of government funding are reported in the Medicare cost reports. The analysis of FY 2019 data found the total value of indirect medical education (IME) payments and Medicare DSH payments totaled \$14 billion for 340B DSH hospitals in 2019. Compared to non-340B short-term acute care hospitals, 340B DSH hospitals receive payments that are more than twice as large (Figure 3) on average.

In addition to these regularly available sources of support, hospitals also received additional support during the COVID-19 pandemic. Hospitals received much of the \$178 billion in provider relief fund grants to help cover additional costs and reduced revenue due to the pandemic.³⁰

FIGURE 3

The Average Additional Medicare Payment for a 340B DSH Hospital is Double Compared to any Other STACH in FY2019



Source: Avalere analysis of FY 2019 Medicare cost reports submitted by 3,209 STACHs. Of those, 1,128 hospitals were participating in 340B as a DSH entity for a full or portion of their cost reporting period based on the enrollment and termination dates in the Office of Pharmacy Affairs (OPA) 340B Database. Note: Inpatient Outlier Payments were unavailable for FY2019

Conclusion

The 340B program was intended to support access to outpatient drugs for uninsured or vulnerable patients through safety-net facilities. The program's design allows eligible hospitals to benefit from steeply discounted prescription drug prices for all patients if they meet the program's eligibility criteria. The 340B program has grown from \$9 billion in sales at the discounted price in 2014 to \$38 billion in 2020.³¹ Yet, this is the fourth iteration of this report spanning eight years and the findings remain the same: despite generating more and more revenue from the 340B program, participating hospitals continue to have low charity care rates, with most 340B hospitals providing below average levels of charity care. To promote a well-functioning 340B program designed to support access for needy patients, and underpinned by sound policy, Congress should reconsider the eligibility criteria for hospitals and incorporate a minimum hospital charity care requirement into 340B hospital eligibility rules.

Appendix A: Additional Information on Charity Care

CHARITY CARE BACKGROUND

Acute-care hospitals often provide charity care to patients who meet certain income requirements. The specific nature of charity care varies by hospital. The Affordable Care Act (ACA) added section 501(r) to the Internal Revenue Code, which requires nonprofit hospitals to meet four key requirements to continue to qualify for federal tax exemption. These four requirements include:

- Establish written financial assistance and emergency medical care policies;
- Limit the amounts charged for emergency or other medically necessary care to individuals eligible for assistance under the hospital's financial assistance policy to not more than the amounts generally billed to individuals who have insurance covering such care;
- Make reasonable efforts to determine whether an individual is eligible for assistance before engaging in extraordinary collection actions against the individual; and
- Conduct a community health needs assessment at least once every three years and adopt an implementation strategy to meet the community health needs identified through such assessment.³²

Each individual hospital develops its own policy regarding the specific financial criteria for an individual treated in the hospital to qualify for charity care. The American Hospital Association's (AHA) voluntary policies and guidelines for hospitals suggest that care should be provided free of charge to patients below 200 percent of the federal poverty level who have "a level of [financial] assets appropriate for the community."³³ However, hospitals are not obligated to follow those voluntary guidelines.

CHARITY CARE DATA

The charity care data analyzed in this report are taken from FY 2012–2019 Medicare cost reports. While the IRS 990 Schedule H forms also include data on charity care, the Medicare cost report forms were used because they include all hospitals, while the IRS forms are only available for non-public hospitals. Specifically, this analysis used the CMS– 2552-10 form, line 23 from worksheet S-10. This line represents the estimated cost of care that was provided to patients approved for charity care. To calculate this amount, hospitals first enter the total charges for care provided to patients approved for charity care on line 20 of the same worksheet.

After entering this amount, hospitals are then instructed to multiply this amount by the hospital-wide cost-to-charge ratio. This is the same ratio the Medicare program uses to convert Medicare charges into estimated costs when determining the payment rates under the Medicare Inpatient Prospective Payment System (IPPS) and Outpatient Prospective Payment System (OPPS).

Finally, hospitals are instructed to subtract any payment they have received from patients who were approved for partial charity care services. This final step is reflected in the amount listed on line 23 of the worksheet, which is the amount used in this report.

Table 1 provides an overview of the number and type of hospitals that were included in the charity care analysis.

TABLE 1: NUMBER OF HOSPITALS INCLUDED IN THE ANALYSIS		
TYPE OF HOSPITAL	340B DSH Hospitals in analysis	Total STACHs (340B and non-340B) in analysis
Short-Term Acute Care Hospitals	1,128	3,209
Nonprofit	867	1,923
Government	240	474
Proprietary	21	812

Appendix B

1. See 42 U.S.C. § 256b (the “340B statute”).
2. AIR340B, “Left Behind: An Analysis of Charity Care Provided by Hospitals Enrolled in the 340B Discount Program,” November 2019.
3. A. Fein. “Exclusive: The 340B Program Soared to \$38 Billion in 2020—Up 27% vs. 2019.” Drug Channels. June 17, 2021. Available at: <https://www.drugchannels.net/2021/06/exclusive-340b-program-soared-to-38.html>.
4. AIR340B, “Left Behind: An Analysis of Charity Care Provided by Hospitals Enrolled in the 340B Discount Program,” November 2019.
5. Government Accountability Office, “340 Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement,” GAO-20-212, January 2020; Government Accountability Office. Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements, December 11, 2019; Government Accountability Office, Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, GAO-18-480: Jun 28, 2018; Government Accountability Office, Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals. GAO-15-442. June 2015; Government Accountability Office. Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement. September 23, 2011.
6. See, e.g., “Hearing Before the Committee on Labor and Human Resources,” U.S. Senate, October 16, 1991; “Statement of the Pharmaceutical Manufacturers Association (PMA)” at 54 (“We understand that the introduction of the bill is a reaction to the price increases to the covered entities caused by the best-price provisions of the Medicaid Rebate Program. That could be addressed by adopting the same approach that is contained in the Department of Veterans Affairs Appropriation Act; namely, to exempt the prices to the covered entities from the Medicaid rebate best price calculations.”)
7. See Veterans Health Care Act of 1992, Pub. L. 102-585, § 601 (exempting prices charged to 340B covered entities from the Medicaid “best price” calculation) and § 602 (creating the 340B program).
8. See 42 U.S.C. § 256b(a)(4)(e).
9. Schmitz R, Limpa-Amara S, Milliner-Waddell J et al. “The PHS 340B drug pricing program: results of a survey of eligible entities,” *Mathematica*, Aug. 2004.
10. C. Hatwig, “340B Drug Pricing Program Update,” AHA Annual Membership Meeting, May 2015.
11. In addition to DSH hospitals, qualifying children’s hospitals, freestanding cancer hospitals, sole community hospitals, rural referral centers, and critical access hospitals can participate in the 340B program.
12. Centers for Medicare & Medicaid Services, “Medicare Disproportionate Share Hospital,” Centers for Medicare & Medicaid Services: Medicare Learning Network, March 2021.
13. A. Vandervelde, “Growth of the 340b Program: Past Trends, Future Projections,” Berkeley Research Group, December 2014.
14. GAO, “340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements,” GAO-20-108, December 2019.
15. GAO, “340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements,” GAO-20-108, December 2019.
16. U.S. House of Representatives Report accompanying H.R. Rep. 102-384 (II) (1992).

17. GAO, "340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements," GAO-20-108, December 2019.
18. GAO, "340B Drug Discount Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements," GAO-21-107, December 2020.
19. GAO, "Drug Discount Program: Characteristics of Hospitals Participating and Not Participating in the 340B Program, June 2018; National Academy of Sciences, "Making Medicines Affordable: A National Imperative (2018)," November 2017.
20. GAO, "Drug Discount Program: Characteristics of Hospitals Participating and Not Participating in the 340B Program, June 2018.
21. Desai SM, McWilliams JM. 340B Drug Pricing Program and hospital provision of uncompensated care. *Am J Manag Care*. 2021 Oct;27(10):432-437.
22. GAO. Discount drug program. Federal oversight of compliance at 340B contract pharmacies needs improvement. Published June 2018. Accessed April 2021. <https://www.gao.gov/assets/gao-18-480.pdf>
23. National Academy of Sciences, "Making Medicines Affordable: A National Imperative (2018)," November 2017.
24. American Hospital Association, "Patient Billing Guidelines," April 2020. Available at: <https://www.aha.org/standardsguidelines/2020-10-15-patient-billing-guidelines>.
25. 26 USC § 501(r).
26. Patient Protection and Affordable Care Act, Disproportionate Share Hospital, Pub. L. No. 111-148, § 9007 (2011); Fed. Reg Vol. 79, No. 250 at 78954.
27. IRS, "Exempt Organizations Hospital Study Executive Summary of Final Report," February 2009.
28. Herring, et al, "Comparing the Value of Nonprofit Hospitals' Tax Exemption to Their Community Benefits," January 2018, Inquiry.
29. Lown Institute, "Lown Institute Hospitals Index," Available at: <https://lowninstitute.org/projects/lown-institute-hospitals-index/> (accessed Oct. 21, 2021).
30. N. Ochieng , J.F. Biniek, M. Musumeci and T. Neuman, "Funding for Health Care Providers During the Pandemic: An Update," KFF, Aug. 20, 2021.
31. A. Fein. "Exclusive: The 340B Program Soared to \$38 Billion in 2020—Up 27% vs. 2019." *Drug Channels*. June 17, 2021. Available at: <https://www.drugchannels.net/2021/06/exclusive-340b-program-soared-to-38.html>.
32. IRS, "Request for Comments Regarding Additional Requirements for Tax-Exempt Hospitals," Notice 2010- 39, <http://www.irs.gov/pub/irs-drop/n-10-39.pdf>.
33. American Hospital Association, "Patient Billing Guidelines," April 2020. Available at: <https://www.aha.org/standardsguidelines/2020-10-15-patient-billing-guidelines>.



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